

## 4. EXPOSURE

The derivation of AWQC for the protection of human health requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. The two primary pathways of human exposure to pollutants present in a particular ambient waterbody that have been considered in deriving AWQC are direct ingestion of drinking water obtained from that waterbody and the consumption of fish/shellfish obtained from that waterbody. The water pathway also includes other exposures from household uses (e.g., showering). The derivation of an AWQC involves the calculation of the maximum water concentration for a pollutant (i.e., the water quality criteria level) that ensures drinking water and/or fish ingestion exposures will not result in human intake of that pollutant in amounts that exceed a specified level based upon the toxicological endpoint of concern.

The equation for noncancer effects is presented again here, in simplified form, to emphasize the exposure-related parameters (in bold). [Note: the RSC parameter also applies to nonlinear low-dose extrapolation for cancer effects and the other exposure parameters apply to all three of the equations (see Section 1.6).]

$$AWQC = RfD \bullet \textbf{RSC} \bullet \frac{(\textbf{BW})}{[\textbf{DI} + (\textbf{FI} \bullet \textbf{BAF})]} \quad (\text{Equation 4-1})$$

where:

AWQC	=	Ambient Water Quality Criterion (mg/L)
RfD	=	Reference dose for noncancer effects (mg/kg-day)
RSC	=	Relative source contribution factor to account for non-water sources of exposure
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)
FI	=	Fish intake (kg/day)
BAF	=	Bioaccumulation factor (L/kg)

The following subsections discuss exposure issues relevant to the 2000 Human Health Methodology: exposure policy issues; consideration of non-water sources of exposure (the Relative Source Contribution approach); and the factors used in AWQC computation. In relevant sections, science policy and risk management decisions made by EPA are discussed.

### 4.1 EXPOSURE POLICY ISSUES

This section discusses broad policy issues related to exposure concerning the major objectives that the Agency believes should be met in setting AWQC.

An Exposure Assessment TSD provides greater detail on numerous topics discussed in this guidance: suggested sources of contaminant concentration and exposure intake information; suggestions of survey methods for obtaining and analyzing exposure data necessary for deriving AWQC; summaries of studies on fish consumption among sport fishers and subsistence fishers; more detailed presentation of parameter values (e.g., fish consumption rates, body weights); and additional guidance on the application of the RSC approach.

#### **4.1.1 Sources of Exposure Associated With Ambient Water**

##### **4.1.1.1 Appropriateness of Including the Drinking Water Pathway in AWQC**

EPA intends to continue including the drinking water exposure pathway in the derivation of its national default human health criteria (AWQC), as has been done since the 1980 AWQC National Guidelines were first published.

EPA recommends inclusion of the drinking water exposure pathway where drinking water is a designated use for the following reasons: (1) Drinking water is a designated use for surface waters under the CWA and, therefore, criteria are needed to assure that this designated use can be protected and maintained. (2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment. (3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants. (4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment.

This policy decision has been supported by the States, most of the public stakeholders, and by external peer reviewers. As with the other exposure parameters, States and authorized Tribes have the flexibility to use alternative intake rates if they believe that drinking water consumption is substantively different than EPA's recommended default assumptions of 2 L/day for adults and 1 L/day for children. EPA recommends that States and authorized Tribes use an intake rate that would be protective of a majority of consumers and will consider whether an alternative assumption is adequately protective of a State's or Tribe's population based on the information or rationale provided at the time EPA reviews State and Tribal water quality standards submissions.

##### **4.1.1.2 Setting Separate AWQC for Drinking Water and Fish Consumption**

In conjunction with the issue of the appropriateness of including the drinking water pathway explicitly in the derivation of AWQC for the protection of human health, EPA intends to continue its practice of setting a single AWQC for both drinking water and fish/shellfish consumption, and a separate AWQC based on ingestion of fish/shellfish alone. This latter criterion applies in those cases where the designated uses of a waterbody include supporting

fishable uses under Section 101(a) of the CWA and, thus, fish or shellfish for human consumption, but not as a drinking water supply source (e.g., non-potable estuarine waters).

EPA does not believe that national water quality criteria for protection of drinking water uses only are particularly useful for two reasons. First, State and Tribal standards for human health are set to protect Section 101(a) uses (e.g., “fishable, swimmable uses”) under the CWA. Second, most waters have multiple designated uses. Additionally, the water quality standards program protects aquatic life. The 2000 Human Health Methodology revisions do not change EPA’s policy to apply aquatic life criteria to protect aquatic species where they are more sensitive (i.e., when human health criteria would not be protective enough) or where human health via fish or water ingestion is not an issue.

#### **4.1.1.3 Incidental Ingestion from Ambient Surface Waters**

The 2000 Human Health Methodology does not routinely include criteria to address incidental ingestion of water from recreational uses. EPA has considered whether there are cases where water quality criteria for the protection of human health based only on fish ingestion (or only criteria for the protection of aquatic life) may not adequately protect recreational users from health effects resulting from incidental water ingestion.

EPA reviewed information that provided estimates of incidental water ingestion rates averaged over time. EPA generally believes that the averaged amount is negligible and will not have any impact on the chemical criteria values representative of both drinking water and fish ingestion. A lack of impact on the criteria values would likely also be true for chemical criteria based on fish consumption only, unless the chemical exhibits no bioaccumulation potential. However, EPA also believes that incidental/accidental water ingestion could be important for the development of microbial contaminant water quality criteria, and for either chemical or microbial criteria for States where recreational uses such as swimming and boating are substantially higher than the national average. EPA also notes that some States have indicated they already have established incidental ingestion rates for use in developing criteria. Therefore, although EPA will not use this intake parameter when deriving its national 304(a) chemical criteria, limited guidance is provided in the Exposure Assessment TSD volume in order to assist States and authorized Tribes that face situations where this intake parameter could be of significance.

### **4.2 CONSIDERATION OF NON-WATER SOURCES OF EXPOSURE WHEN SETTING AWQC**

#### **4.2.1 Policy Background**

The 2000 Human Health Methodology uses different approaches for addressing non-water exposure pathways in setting AWQC for the protection of human health depending upon the toxicological endpoint of concern. With those substances for which the appropriate toxic endpoint is carcinogenicity based on a linear low-dose extrapolation, only the two water sources (i.e., drinking water and fish ingestion) are considered in the derivation of the AWQC. Non-water

sources are not considered explicitly. In the case of carcinogens based on linear low-dose extrapolation, the AWQC is being determined with respect to the *incremental* lifetime risk posed by a substance's presence in water, and is not being set with regard to an individual's total risk from all sources of exposure. Thus, the AWQC represents the water concentration that would be expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

Furthermore, health-based criteria values for one medium based on linear low-dose extrapolation typically vary from values for other media in terms of the concentration value, and often the associated risk level. Therefore, the RSC concept could not even theoretically apply unless all risk assessments for a particular carcinogen based on linear low-dose extrapolation resulted in the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk value and level.

In the case of substances for which the AWQC is set on the basis of a carcinogen based on a nonlinear low-dose extrapolation or for a noncancer endpoint where a threshold is assumed to exist, non-water exposures are considered when deriving the AWQC using the RSC approach. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure does not exceed that threshold level.

There has been some discussion of whether it is, in fact, necessary in most cases to explicitly account for other sources of exposure when computing the AWQC for pollutants exhibiting threshold effects. It has been argued that because of the conservative assumptions generally incorporated in the calculation of RfDs (or POD/UF values) used as the basis for the AWQC derivation, total exposures slightly exceeding the RfD are unlikely to produce adverse effects.

EPA emphasizes that the purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD or the POD/UF. The policy of considering multiple sources of exposure when deriving health-based criteria has become common in EPA's program office risk characterizations and criteria and standard-setting actions. Numerous EPA workgroups have evaluated the appropriateness of factoring in such exposures, and the Agency concludes that it is important for adequately protecting human health. Consequently, EPA risk management policy has evolved significantly over the last six years. Various EPA program initiatives and policy documents regarding aggregate exposure and cumulative risk have been developed, including the consideration of inhalation and dermal exposures. Additionally, accounting for other exposures has been included in recent mandates (e.g., the Food Quality Protection Act) and, thus, is becoming a requirement for the Agency. The Exposure Decision Tree approach has been shared with other EPA offices, and efforts to coordinate policies on aggregate exposure, where appropriate, have begun. EPA intends to continue developing policy guidance on the RSC issue and guidance to address the concern that human health may not be adequately protected if criteria allow for higher levels of

exposure that, combined, may exceed the RfD or POD/UF. EPA also intends to refine the 2000 Human Health Methodology in the future to incorporate additional guidance on inhalation and dermal exposures. As stated previously, EPA is required to derive national water quality criteria under Section 304(a) of the CWA and does not intend to derive site-specific criteria. However, States and authorized Tribes have the flexibility to make alternative exposure and RSC estimates based on local data, and EPA strongly encourages this.

Uncertainty factors used in the derivation of the RfD (or POD/UF) to account for intra- and interspecies variability and the incompleteness of the toxicity data set(s)/animal studies are specifically relevant to the chemical's internal toxicological action, irrespective of the sources of exposure that humans may be experiencing. The Agency's policy is to consider and account for other sources of exposure in order to set protective health criteria. EPA believes that multiple route exposures may be particularly important when uncertainty factors associated with the RfD are small. Although EPA is well aware that RfDs are not all equivalent in their derivation, EPA does not believe that uncertainty in the toxicological data should result in less stringent criteria by ignoring exposure sources. However, the RSC policy approach does allow less stringent assumptions when multiple sources of exposure are not anticipated.

The AWQC are designed to be protective criteria, generally applicable to the waters of the United States. While EPA cannot quantitatively predict the actual human health risk associated with combined exposures above the RfD or POD/UF, a combination of health criteria for multiple media exceeding the RfD or POD/UF may not be sufficiently protective. Therefore, EPA's policy is to routinely account for all sources and routes of non-occupational exposure when setting AWQC for noncarcinogens and for carcinogens based on nonlinear low-dose extrapolations. EPA believes that maintaining total exposure below the RfD (or POD/UF) is a reasonable health goal and that there are circumstances where health-based criteria for a chemical should not exceed the RfD (or POD/UF), either alone (if only one criterion is relevant, along with other intake sources considered as background exposures) or in combination. EPA believes its RSC policy ensures this goal.

Also, given the inability to reasonably predict future changes in exposure patterns, the uncertainties in the exposure estimates due to typical data inadequacy, possible unknown sources of exposure, and the potential for some populations to experience greater exposures than indicated by the available data, EPA believes that utilizing the entire RfD (or POD/UF) does not ensure adequate protection.

#### **4.2.2 The Exposure Decision Tree Approach**

As indicated in Section 1, EPA has, in the past, used a "subtraction" method to account for multiple sources of exposure to pollutants. In the subtraction method, other sources of exposure (i.e., those other than the drinking water and fish exposures) are subtracted from the RfD (or POD/UF). However, EPA also previously used a "percentage" method for the same purpose. In this approach, the percentage of total exposure typically accounted for by the exposure source for which the criterion is being determined, referred to as the relative source

contribution (RSC), is applied to the RfD to determine the maximum amount of the RfD “apportioned” to that source. With both procedures, a “ceiling” level of 80 percent of the RfD and a “floor level” of 20 percent of the RfD are applied.

The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. The percentage method is recommended in the context of the above goals when multiple media criteria are at issue. The percentage method does not simply depend on the amount of a contaminant in the prospective criterion source only. It is intended to reflect health considerations, the relative portions of other sources, and the likelihood for ever-changing levels in each of those multiple sources (due to ever-changing sources of emissions and discharges). Rather than simply defaulting in every instance, the Agency attempts to compare multiple source exposures with one another to estimate their relative contribution to the total—given that understanding the degree to which their concentrations vary, or making any distributional analysis, is often not possible. The criteria levels, when multiple criteria are at issue, are based on the actual levels, with an assumption that there may be enough relative variability such that an apportionment (relating that percentage to the RfD) is a reasonable way of accounting for the uncertainty regarding that variability.

The specific RSC approach recommended by EPA, which we will use for the derivation of AWQC for noncarcinogens and carcinogens assessed using nonlinear low-dose extrapolation, is called the Exposure Decision Tree and is described below. To account for exposures from other media when setting an AWQC (i.e., non-drinking water/non-fish ingestion exposures, and inhalation or dermal exposures), the Exposure Decision Tree for determining proposed RfD or POD/UF apportionments represents a method of comprehensively assessing a chemical for water quality criteria development. This method considers the adequacy of available exposure data, levels of exposure, relevant sources/media of exposure, and regulatory agendas (i.e., whether there are multiple health-based criteria or regulatory standards for the same chemical). The Decision Tree addresses most of the disadvantages associated with the exclusive use of either the percentage or subtraction approaches, because they are not arbitrarily chosen prior to determining the following: specific population(s) of concern, whether these populations are relevant to multiple-source exposures for the chemical in question (i.e., whether the population is actually or potentially experiencing exposure from multiple sources), and whether levels of exposure, regulatory agendas, or other circumstances make apportionment of the RfD or POD/UF desirable. Both subtraction and percentage methods are potentially utilized under different circumstances with the Exposure Decision Tree approach, and the Decision Tree is recommended with the idea that there is enough flexibility to use other procedures if information on the contaminant in question suggests it is not appropriate to follow the Decision Tree. EPA recognizes that there may be other valid approaches in addition to the Exposure Decision Tree.

The Exposure Decision Tree approach allows flexibility in the RfD (or POD/UF) apportionment among sources of exposure. When adequate data are available, they are used to make protective exposure estimates for the population(s) of concern. When other sources or routes of exposure are anticipated but data are not adequate, there is an even greater need to make sure that public health protection is achieved. For these circumstances, a series of

qualitative alternatives is used (with the less adequate data or default assumptions) that allow for the inadequacies of the data while protecting human health. Specifically, the Decision Tree makes use of chemical information when actual monitoring data are inadequate. It considers information on the chemical/physical properties, uses of the chemical, and environmental fate and transformation, as well as the likelihood of occurrence in various media. Review of such information, when available, and determination of a reasonable exposure characterization for the chemical will result in a water quality criterion that more accurately reflects exposures than automatically using a default value. Although the 20 percent default will still generally be used when information is not adequate, the need for using it should be reduced. There may also be some situations where EPA would consider the use of an 80 percent default (see Section 4.2.3).

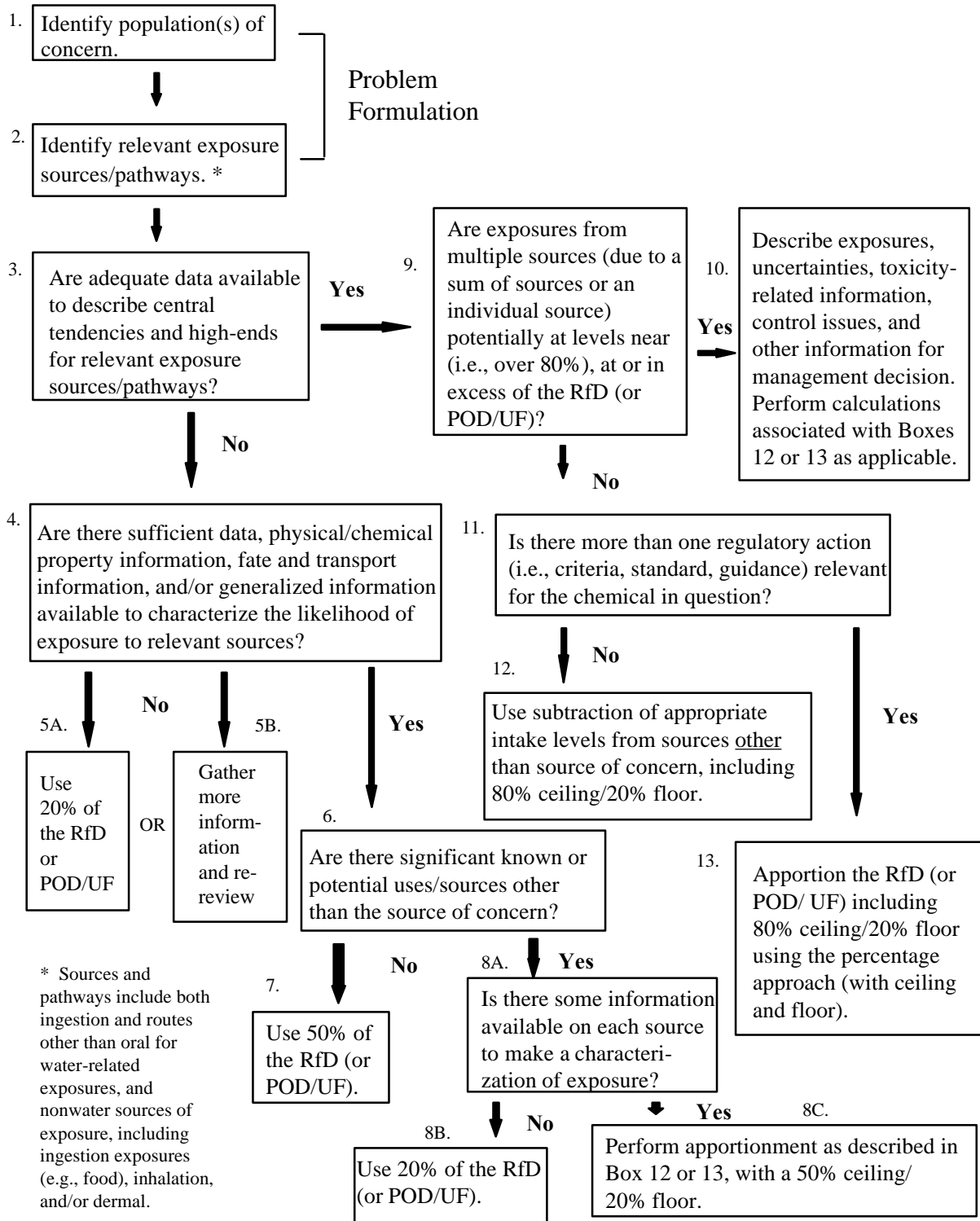
The Decision Tree also allows for use of either the subtraction or percentage method to account for other exposures, depending on whether one or more health-based criterion is relevant for the chemical in question. The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. In these cases, other sources of exposure can be considered “background” and can be subtracted from the RfD (or POD/UF).

EPA cautions States and Tribes when using the subtraction method in these circumstances. The subtraction method results in a criterion allowing the maximum possible chemical concentration in water after subtracting other sources. As such, it removes any cushion between pre-criteria levels (i.e., actual “current” levels) and the RfD, thereby setting criteria at the highest levels short of exceeding the RfD. It is somewhat counter to the goals of the CWA for maintaining and restoring the nation’s waters. It is also directly counter to Agency policies, explicitly stated in numerous programs, regarding pollution prevention. EPA has advocated that it is good health policy to set criteria such that exposures are kept low when current levels are already low. The subtraction method generally results in criteria levels of a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to such goals. In fact, many chemicals have pre-criteria levels in environmental media substantially lower (compared to the RfD) than the resulting criteria allow.

When more than one criterion is relevant to a particular chemical, apportioning the RfD (or POD/UF) via the percentage method is considered appropriate to ensure that the combination of criteria and, thus, the potential for resulting exposures do not exceed the RfD (or POD/UF). The Exposure Decision Tree (with numbered boxes) is shown in Figure 4-1. The explanation in the text on the following pages must be read in tandem with the Decision Tree figure; the text in each box of the figure only nominally identifies the process and conditions for determining the outcome for that step of the Decision Tree. The underlying objective is to maintain total exposure below the RfD (or POD/UF) while generally avoiding an extremely low limit in a single medium that represents just a nominal fraction of the total exposure. To meet this objective, all proposed numeric limits lie between 80 percent and 20 percent of the RfD (or POD/UF). Again, EPA will use the Exposure Decision Tree approach when deriving its AWQC but also recognizes that departures from the approach may be appropriate in certain cases. EPA understands that there may be situations where the Decision Tree procedure is not practicable or

Figure 4-1

Exposure Decision Tree for Defining Proposed RfD (or POD/UF) Apportionment





may be simply irrelevant after considering the properties, uses, and sources of the chemical in question. EPA endorses such flexibility by States and authorized Tribes when developing alternative water quality criteria in order to choose other procedures that are more appropriate for setting health-based criteria and, perhaps, apportioning the RfD or POD/UF, as long as reasons are given as to why it is not appropriate to follow the Exposure Decision Tree approach and as long as the steps taken to evaluate the potential sources and levels of exposure are clearly described. Often, however, the common situation of multiple exposure sources for a chemical is likely to merit a Decision Tree evaluation for the purpose of developing human health water quality criteria for a given chemical.

It is clear that this will be an interactive process; input by exposure assessors will be provided to, and received from, risk managers throughout the process, given that there may be significant implications regarding control issues (i.e., cost/feasibility), environmental justice issues, etc. In cases where the Decision Tree is not chosen, communication and concurrence about the decision rationale and the alternative water quality criteria are of great importance.

Descriptions of the boxes within the Decision Tree are separated by the following process headings to facilitate an understanding of the major considerations involved. The decision to perform, or not to perform, an apportionment could actually be made at several points during the Decision Tree process. Working through the process is most helpful for identifying possible exposure sources and the potential for exposure, determining the relevancy of the Decision Tree to developing an AWQC for a particular chemical and, possibly, determining the appropriateness of using an alternative approach to account for overall exposure. “Relevancy” here means determining whether more than one criterion, standard, or other guidance is being planned or is in existence for the chemical in question. Additional guidance for States and Tribes that wish to use the Exposure Decision Tree is provided in the Exposure Assessment TSD.

#### **4.2.2.1 Problem Formulation**

Initial Decision Tree discussion centers around the first two boxes: identification of population(s) of concern (Box 1) and identification of relevant exposure sources and pathways (Box 2). The term “problem formulation” refers to evaluating the population(s) and sources of exposure in a manner that allows determination of the potential for the population of concern to experience exposures from multiple sources for the chemical in question. Also, the data for the chemical in question must be representative of each source/medium of exposure and be relevant to the identified population(s). Evaluation includes determining whether the levels, multiple criteria or regulatory standards, or other circumstances make apportionment of the RfD or POD/UF reasonable. The initial problem formulation also determines the exposure parameters chosen, the intake assumptions chosen for each route, and any environmental justice or other social issues that aid in determining the population of concern. The term “data,” as used here and discussed throughout this section, refers to ambient sampling data (whether from Federal, regional, State, or area-specific studies) and not internal human exposure measurements.

#### 4.2.2.2 Data Adequacy

In Box 3, it is necessary that adequate data exist for the relevant sources/pathways of exposure if one is to avoid using default procedures. The adequacy of data is a professional judgment for each individual chemical of concern, but EPA recommends that the minimum acceptable data for Box 3 are exposure distributions that can be used to determine, with an acceptable 95 percent confidence interval, the central tendency and high-end exposure levels for each source. In fact, distributional data may exist for some or most of the sources of exposure.

There are numerous factors to consider in order to determine whether a dataset is adequate. These include: (1) sample size (i.e., the number of data points); (2) whether the data set is a random sample representative of the target population (if not, estimates drawn from it may be biased no matter how large the sample); (3) the magnitude of the error that can be tolerated in the estimate (estimator precision); (4) the sample size needed to achieve a given precision for a given parameter (e.g., a larger sample is needed to precisely estimate an upper percentile than a mean or median value); (5) an acceptable analytical method detection limit; and (6) the functional form and variability of the underlying distribution, which determines the estimator precision (e.g., whether the distribution is normal or lognormal and whether the standard deviation is 1 or 10). Lack of information may prevent assessment of each of these factors; monitoring study reports often fail to include background information or sufficient summary statistics (and rarely the raw data) to completely characterize data adequacy. Thus, a case-by-case determination of data adequacy may be necessary.

That being stated, there are some guidelines, as presented below, that lead to a rough rule-of-thumb on what constitutes an “adequate” sample size for exposure assessment. Again, first and foremost, the representativeness of the data for the population evaluated and the analytical quality of the data must be acceptable. If so, the primary objective then becomes estimating an upper percentile (e.g., say the 90<sup>th</sup>) and a central tendency value of some exposure distribution based on a random sample from the distribution. Assuming that the distribution of exposures is unknown, a nonparametric estimate of the 90<sup>th</sup> percentile is required. The required estimate, based on a random sample of  $n$  observations from a target population, is obtained by ranking the data from smallest to largest and selecting the observation whose rank is 1 greater than the largest integer in the product of 0.9 times  $n$ . For example, in a data set of 25 points, the nonparametric estimate of the 90<sup>th</sup> percentile is the 23rd largest observation.

In addition to this point estimate, it is useful to have an upper confidence bound on the 90<sup>th</sup> percentile. To find the rank of the order statistic that gives an upper 95 percent confidence limit on the 90<sup>th</sup> percentile, the smallest value of  $r$  that satisfies the following formula is determined:

$$0.95 \approx \sum_{i=0}^{r-1} \binom{n}{i} 0.9^i 0.1^{n-i} \quad (\text{Equation 4-2})$$

where:

$r$  = the rank order of the observation  
 $n$  = the number of observations  
 $i$  = integer from 0 to  $r - 1$

For relatively small data sets, the above formula will lead to selecting the largest observation as the upper confidence limit on the 90<sup>th</sup> percentile. However, the problem with using the maximum is that, in many environmental datasets, the largest observation is an outlier and would provide an unrealistic upper bound on the 90<sup>th</sup> percentile. It would, therefore, be preferable if the sample size  $n$  were large enough so that the formula yielded the second largest observation as the confidence limit (see for example Gibbons, 1971).

This motivates establishing the following criterion for setting an “adequate” sample size: pick the smallest  $n$  such that the nonparametric upper 95 percent confidence limit on the 90<sup>th</sup> percentile is the second largest value. Application of the above formula with  $r$  set to  $n-1$  yields  $n = 45$  for this minimum sample size.

For the upper 95 percent confidence limit to be a useful indicator of a high-end exposure, it must not be overly conservative (too large relative to the 90<sup>th</sup> percentile). It is, therefore, of interest to estimate the expected magnitude of the ratio of the upper 95 percent confidence limit to the 90<sup>th</sup> percentile. This quantity generally cannot be computed, since it is a function of the unknown distribution. However, to get a rough idea of its value, consider the particular case of a normal distribution. If the coefficient of variation (i.e., the standard deviation divided by the mean) is between 0.5 and 2.0, the expected value of the ratio in samples of 45 will be approximately 1.17 to 1.31; i.e., the upper 95 percent confidence limit will be only about 17 to 31 percent greater than the 90<sup>th</sup> percentile on the average.

It should be noted that the nonparametric estimate of the 95 percent upper confidence limit based on the second largest value can be obtained even if the data set has only two detects (it is assumed that the two detects are greater than the detection limit associated with all non-detects). This is an argument for using nonparametric rather than parametric estimation, since use of parametric methods would require more detected values. On the other hand, if non-detects were not a problem and the underlying distribution were known, a parametric estimate of the 90<sup>th</sup> percentile would generally be more precise.

As stated above, adequacy also depends on whether the samples are relevant to and representative of the population at risk. Data may, therefore, be adequate for some decisions and inadequate for others; this determination requires some professional judgment.

If the answer to Box 3 is no, based on the above determination of adequacy, then the decision tree moves to Box 4. As suggested by the separate boxes, the available data that will be reviewed as part of Box 4 do not meet the requirements necessary for Box 3. In Box 4, any limited data that are available (in addition to information about the chemical/physical properties, uses, and environmental fate and transformation, as well as any other information that would characterize the likelihood of exposure from various media for the chemical) are evaluated to make a qualitative determination of the relation of one exposure source to another. Although this information should always be reviewed at the outset, it is recommended that this information also be used to estimate the health-based water quality criteria. The estimate should be rather conservative (as indicated in the Decision Tree), given that it is either not based on actual monitoring data or is based on data that has been considered to be inadequate for a more accurate quantitative estimate. Therefore, greater uncertainties exist and accounting for variability is not really possible. Whether the available data are adequate and sufficiently representative will likely vary from chemical to chemical and may depend on the population of concern. If there are some data and/or other information to make a characterization of exposure, a determination can be made as to whether there are significant known or potential uses for the chemical/sources of exposure other than the source of concern (i.e., in this case, the drinking water and fish intakes relevant to developing an AWQC) that would allow one to anticipate/quantify those exposures (Box 6). If there are not, then it is recommended that 50 percent of the RfD or POD/UF can be safely apportioned to the source of concern (Box 7). While this leaves half of the RfD or POD/UF unapportioned, it is recommended as the maximum apportionment due to the lack of data needed to more accurately quantify actual or potential exposures. If the answer to the question in Box 6 is yes (there is multiple source information available for the exposures of concern), and some information is available on each source of exposure (Box 8A), apply the procedure in either Box 12 or Box 13 (depending on whether one or more criterion is relevant to the chemical), using a 50 percent ceiling (Box 8C)—again due to the lack of adequate data. If the answer to the question in Box 8A is no (there is no available information to characterize exposure), then the 20 percent default of the RfD or POD/UF is used (Box 8B).

If the answer to the question in Box 4 is no; that is, there are not sufficient data/information to characterize exposure, EPA intends to generally use the “default” assumption of 20 percent of the RfD or POD/UF (Box 5A) when deriving or revising the AWQC. It may be better to gather more data or information and re-review when this information becomes available (Box 5B). EPA has done this on occasion when resources permit the acquisition of additional data to enable better estimates of exposure instead of the default. If this is not possible, then the assumption of 20 percent of the RfD or POD/UF (Box 5A) should be used. Box 5A is likely to be used infrequently with the Exposure Decision Tree approach, given that the information described in Box 4 should be available in most cases. However, EPA intends to use 20 percent of the RfD (or POD/UF), which has also been used in past water program regulations, as the default value.

#### **4.2.2.3 Regulatory Actions**

If there are adequate data available to describe the central tendencies and high ends from each exposure source/pathway, then the levels of exposure relative to the RfD or POD/UF are compared (Box 9). If the levels of exposure for the chemical in question are not near (currently defined as greater than 80 percent), at, or in excess of the RfD or POD/UF, then a subsequent determination is made (Box 11) as to whether there is more than one health-based criterion or regulatory action relevant for the given chemical (i.e., more than one medium-specific criterion, standard or other guidance being planned, performed or in existence for the chemical). The subtraction method is considered acceptable when only one criterion (standard, etc.) is relevant for a particular chemical. In these cases, other sources of exposure can be considered “background” and can be subtracted from the RfD (or POD/UF). When more than one criterion is relevant to a particular chemical, apportioning the RfD (or POD/UF) via the percentage method is considered appropriate to ensure that the combination of health criteria, and thus the potential for resulting exposures, do not exceed the RfD (or POD/UF).

As indicated in Section 2, for EPA’s national 304(a) criteria, the RSC intake estimates of non-water exposures (e.g., non-fish dietary exposures) will be based on arithmetic mean values when data are available. The assumed body weight used in calculating the national criteria will also be based on average values. The drinking water and fish intake values are 90<sup>th</sup> percentile estimates. EPA believes that these assumptions will be protective of a majority of the population and recommends them for State and Tribal use. However, States and authorized Tribes have the flexibility to choose alternative intake rate and exposure estimate assumptions to protect specific population groups that they have chosen.

#### **4.2.2.4 Apportionment Decisions**

If the answer to the question in Box 11 is no (there is not more than one relevant medium-specific criterion/regulatory action), then the recommended method for setting a health-based water quality criterion is to utilize a subtraction calculation (Box 12). Specifically, appropriate intake values for each exposure source other than the source of concern are subtracted out. EPA will rely on average values commonly used in the Agency for food ingestion and inhalation rates, combined with mean contaminant concentration values, for calculating RSC estimates to subtract. Alternatively, contaminant concentrations could be selected based on the variability associated with those concentrations for each source. This implies that a case-by-case determination of the variability and the resulting intake chosen would be made, as each chemical evaluated can be expected to have different variations in concentration associated with each source of intake. However, EPA anticipates that the available data for most contaminants will not allow this for determination (based on past experience). Guidance addressing this possibility is addressed in the Exposure Assessment TSD. EPA does not recommend that high-end intakes be subtracted for every exposure source, since the combination may not be representative of any actually exposed population or individual. The subtraction method would also include an 80 percent ceiling and a 20 percent floor.

If the answer to the question in Box 11 is yes (there is more than one medium-specific criterion/regulation relevant), then the recommended method for setting health-based water quality criteria is to apportion the RfD or POD/UF among those sources for which health-based criteria are being set (Box 13). This is done via a percentage approach (with a ceiling and floor). This simply refers to the percentage of overall exposure contributed by an individual exposure source. For example, if for a particular chemical, drinking water were to represent half of total exposure and diet were to represent the other half, then the drinking water contribution (or RSC) would be 50 percent. The health-based criteria would, in turn, be set at 50 percent of the RfD or POD/UF. This method also utilizes an appropriate combination of intake values for each exposure source based on values commonly used in the Agency for food ingestion and inhalation rates, combined with mean contaminant concentration values.

Finally, if the levels of exposure for the chemical in question are near (currently defined as greater than 80 percent), at, or in excess of the RfD or POD/UF (i.e., the answer in Box 9 is yes), then the estimates of exposures and related uncertainties, recommended apportionment (either box 12 or 13), toxicity-related information, control issues, and other information are to be presented to managers for a decision (Box 10). The high levels referred to in Box 9 may be due to one source contributing that high level (while other sources contribute relatively little) or due to more than one source contributing levels that, in combination, approach or exceed the RfD or POD/UF. Management input may be necessary due to the control issues (i.e., cost and feasibility concerns), especially when multiple criteria are at issue. In practice, risk managers are routinely a part of decisions regarding regulatory actions and will be involved with any recommended outcome of the Exposure Decision Tree or, for that matter, any alternative to the Exposure Decision Tree. However, because exposures approach or exceed the RfD or POD/UF and because the feasibility of controlling different sources of exposure are complicated issues, risk managers will especially need to be directly involved in final decisions in these circumstances.

It is emphasized here that the procedures in these circumstances are not different than the procedures when exposures are not at or above the RfD (or POD/UF). Therefore, in these cases, estimates should be performed as with Boxes 11, 12, and 13. The recommendation should be made based on health-based considerations only, just as when the chemical in question was not a Box 10 situation. If the chemical is relevant to one health criterion or regulatory action only, the other sources of exposure could be subtracted from the RfD or POD/UF to determine if there is any leftover amount for setting the criterion. If the chemical is a multiple media criteria issue, then an apportionment should be made, even though it is possible that all sources would need to be reduced. Regardless of the outcome of Box 9, all apportionments made (via the methods of Boxes 12 or 13) should include a presentation of the uncertainty in the estimate and in the RfD or POD/UF for a more complete characterization.

The process for a Box 10 situation (versus a situation that is not) differs in that the presentations for Boxes 12 and 13 are based on apportionments (following the review of available information and a determination of appropriate exposure parameters) that must address additional control issues and may result in more selective reductions. With Box 10, one or several criteria possibilities (“scenarios”) could be presented for comparison along with implications of the effects

of various control options. It is appropriate to present information in this manner to risk managers given the complexity of these additional control issues.

#### **4.2.3 Additional Points of Clarification on the Exposure Decision Tree Approach for Setting AWQC**

As with Box 9, if a determination is made in Box 8A (i.e., information is available to characterize exposure) that exposures are near, at, or above the RfD (or POD/UF) based on the available information, the apportionments made need to be presented to risk managers for decision. If information is lacking on some of the multiple exposure sources, then EPA would use a default of 20 percent of the RfD or POD/UF (Box 8B).

Results of both Boxes 12 and 13 rely on the 80 percent ceiling and 20 percent floor. The 80 percent ceiling was implemented to ensure that the health-based goal will be low enough to provide adequate protection for individuals whose total exposure to a contaminant is, due to any of the exposure sources, higher than currently indicated by the available data. This also increases the margin of safety to account for possible unknown sources of exposure. The 20 percent floor has been traditionally rationalized to prevent a situation where small fractional exposures are being controlled. That is, below that point, it is more appropriate to reduce other sources of exposure, rather than promulgating standards for *de minimus* reductions in overall exposure.

If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80 percent ceiling. EPA qualifies this policy with the understanding that as its policy on cumulative risk assessment continues to develop, the 80 percent RSC may prove to be underprotective.

In the cases of pollutants for which substantial data sets describing exposures across all anticipated pathways of exposure exist, and probabilistic analyses have been conducted based on those data, consideration will be given to the results of those assessments as part of the Exposure Decision Tree approach for setting AWQC.

For many chemicals, the rate of absorption from ingestion can differ substantially from absorption by inhalation. There is also available information for some chemicals that demonstrates appreciable differences in gastrointestinal absorption depending on whether the chemical is ingested from water, soil, or food. For some contaminants, the absorption of the contaminant from food can differ appreciably for plant compared with animal food products. Regardless of the apportionment approach used, EPA recommends using existing data on differences in bioavailability between water, air, soils, and different foods when estimating total exposure for use in apportioning the RfD or POD/UF. The Agency has developed such exposure estimates for cadmium (USEPA, 1994). In the absence of data, EPA will assume equal rates of absorption from different routes and sources of exposure.

#### **4.2.4 Quantification of Exposure**

When selecting contaminant concentration values in environmental media and exposure intake values for the RSC analysis, it is important to realize that each value selected (including those recommended as default assumptions in the AWQC equation) may be associated with a distribution of values for that parameter. Determining how various subgroups fall within the distributions of overall exposure and how the combination of exposure variables defines what population is being protected is a complicated and, perhaps, unmanageable task, depending on the amount of information available on each exposure factor included. Many times, the default assumptions used in EPA risk assessments are derived from the evaluation of numerous studies and are considered to generally represent a particular population group or a national average. Therefore, describing with certainty the exact percentile of a particular population that is protected with a resulting criteria is often not possible.

By and large, the AWQC are derived to protect the majority of the general population from chronic adverse health effects. However, as stated above in Section 4.1.1.1, States and authorized Tribes are encouraged to consider protecting population groups that they determine are at greater risk and, thus, would be better protected using alternative exposure assumptions. The ultimate choice of the contaminant concentrations used in the RSC estimate and the exposure intake rates requires the use of professional judgment. This is discussed in greater detail in the Exposure Assessment TSD.

#### **4.2.5 Inclusion of Inhalation and Dermal Exposures**

EPA intends to develop policy guidelines to apply to this Methodology for explicitly incorporating inhalation and dermal exposures. When estimating overall exposure to pollutants for AWQC development, EPA believes that the sources of inhalation and dermal exposures considered should include, on a case-by-case basis, both non-oral exposures from water and other inhalation and dermal sources (e.g., ambient or indoor air, soil). When the policy guidelines are completed, this Methodology will be refined to include that guidance.

A number of drinking water contaminants are volatile and thus diffuse from water into the air where they may be inhaled. In addition, drinking water is used for bathing and, thus, there is at least the possibility that some contaminants in water may be dermally absorbed. Volatilization may increase exposure via inhalation and decrease exposure via ingestion and dermal absorption. The net effect of volatilization and dermal absorption upon total exposure to volatile drinking water contaminants is unclear in some cases and varies from chemical to chemical. Dermal exposures are also important to consider for certain population groups, such as children and other groups with high soil contact.

With regard to additional non-water related exposures, it is clear that the type and magnitude of toxicity produced via inhalation, ingestion, and dermal contact may differ; that is, the route of exposure can affect absorption of a chemical and can otherwise modify its toxicity. For example, an inhaled chemical such as hydrogen fluoride may produce localized effects on the



lung that are not observed (or only observed at much higher doses) when the chemical is administered orally. Also, the active form of a chemical (and principal toxicity) can be the parent compound and/or one or more metabolites. With this Methodology, EPA recommends that differences in absorption and toxicity by different routes of exposure be determined and accounted for in dose estimates and applied to the exposure assessment. EPA acknowledges that the issue of whether the doses received from inhalation and ingestion exposures are cumulative (i.e., toward the same threshold of toxicity) is complicated. Such a determination involves evaluating the chemical's physical characteristics, speciation, and reactivity. A chemical may also exhibit different metabolism by inhalation versus oral exposure and may not typically be metabolized by all tissues. In addition, a metabolite may be much more or much less toxic than the parent compound. Certainly with a systemic effect, if the chemical absorbed via different routes enters the bloodstream, then there is some likelihood that it will contact the same target organ. Attention also needs to be given to the fact that both the RfD and RfC are derived based on the administered level. Toxicologists generally believe that the effective concentration of the active form of a chemical(s) at the site(s) of action determines the toxicity. If specific differences between routes of exposure are not known, it may be reasonable to assume that the internal concentration at the site from any route contributes as much to the same effect as any other route. A default of assuming equal absorption has often been used. However, for many of the chemicals that the Agency has reviewed, there is a substantial amount of information already known to determine differences in rates of absorption. For example, absorption is, in part, a function of blood solubility (i.e., Henry's Constant) and better estimations than the default can be made.

The RSC analyses that accompany the 2000 Human Health Methodology accommodate inclusion of inhalation exposures. Even if different target organs are involved between different routes of exposure, a conservative policy may be appropriate to keep all exposures below a certain level. A possible alternative is to set allowable levels (via an equation) such that the total of ingestion exposures over the ingestion RfD added to the total of inhalation exposures over the inhalation RfC is not greater than 1 (Note: the RfD is typically presented in mg/kg-day and the RfC is in mg/m<sup>3</sup>). Again, EPA intends to develop guidance for this Methodology to explicitly incorporate inhalation and dermal exposures, and will refine the Methodology when that guidance is completed.

#### **4.3 EXPOSURE FACTORS USED IN THE AWQC COMPUTATION**

This section presents values for the specific exposure factors that EPA will use in the derivation of AWQC. These include human body weight, drinking water consumption rates, and fish ingestion rates.

When choosing exposure factor values to include in the derivation of a criterion for a given pollutant, EPA recommends considering values that are relevant to population(s) that is (are) most susceptible to that pollutant. In addition, highly exposed populations should be considered when setting criteria. In general, exposure factor values specific to adults and relevant to lifetime exposures are the most appropriate values to consider when determining criteria to protect against effects from long-term exposure which, by and large, the human health criteria are

derived to protect. However, infants and children may have higher rates of water and food consumption per unit body weight compared with adults and also may be more susceptible to some pollutants than adults (USEPA, 1997a). There may be instances where acute or subchronic developmental toxicity makes children the population group of concern. In addition, exposure of pregnant women to certain toxic chemicals may cause developmental effects in the fetus (USEPA, 1997b). Exposures resulting in developmental effects may be of concern for some contaminants and should be considered along with information applicable to long-term health effects when setting AWQC. (See Section 3.2 for further discussion of this issue.) Short-term exposure may include multiple intermittent or continuous exposures occurring over a week or so. Exposure factor values relevant for considering chronic toxicity, as well as exposure factor values relevant for short-term exposure developmental concerns, that could result in adverse health effects are discussed in the sections below. In appropriate situations, EPA may consider developing criteria for developmental health effects based on exposure factor values specific to children or to women of childbearing age. EPA encourages States and Tribes to do the same when health risks are associated with short-term exposures.

EPA believes that the recommended exposure factor default intakes for adults in chronic exposure situations are adequately protective of the population over a lifetime. In providing additional exposure intake values for highly exposed subpopulations (e.g., sport anglers, subsistence fishers), EPA is providing flexibility for States and authorized Tribes to establish criteria specifically targeted to provide additional protection using adjusted values for exposure parameters for body weight, drinking water intake, and fish consumption. The exposure factor values provided for women of childbearing age and children would only be used in the circumstances indicated above.

Each of the following sections recommends exposure parameter values for use in developing AWQC. These are based on both science policy decisions that consider the best available data, as well as risk management judgments regarding the overall protection afforded by the choice in the derivation of AWQC. These will be used by EPA to derive new, or revise existing, 304(a) national criteria.

#### **4.3.1 Human Body Weight Values for Dose Calculations**

The source of data for default human body weights used in deriving the AWQC is the third *National Health and Nutrition Examination Survey* (NHANES III). NHANES III represents a very large interview and examination endeavor of the National Center for Health Statistics (NCHS) and included participation from the Centers for Disease Control (CDC). The NHANES III was conducted on a nationwide probability sample of over 30,000 persons from the civilian, non-institutionalized population of the United States. The survey began in October 1988 and was completed in October 1994 (WESTAT, 2000; McDowell, 2000). Body weight data were taken from the NHANES III Examination Data File. Sampling weights were applied to all persons examined in the Mobile Examination Centers (MECs) or at home, as was recommended by the NHANES data analysts (WESTAT, 2000).

The NHANES III survey has numerous strengths and very few weaknesses. Its primary strengths are the national representativeness, large sample size, and precise estimates due to this large sample size. Another strength is its high response rate; the examination rate was 73 percent overall, 89 percent for children under 1 year old, and approximately 85 percent for children 1 to 5 years old (McDowell, 2000). Interview response rates were even higher, but the body weight data come from the NHANES examinations; that is, all body weights were carefully measured by survey staff, rather than the use of self-reported body weights. The only significant potential weakness of the NHANES data is the fact that the data are now between 6 and 12 years old. Given that there were upward trends in body weight from NHANES II to NHANES III, and that NCHS has indicated the prevalence of overweight people increased in all age groups, the data could underestimate current body weights if that trend has continued (WESTAT, 2000).

The NHANES III collected standard body measurements of sample subjects, including height and weight, that were made at various times of the day and in different seasons of the year. This technique was used because one's weight may vary between winter and summer and may fluctuate with recency of food and water intake and other daily activities (McDowell, 2000).

As with the other exposure assumptions, States and authorized Tribes are encouraged to use alternative body weight assumptions for population groups other than the general population and to use local or regional data over default values as more representative of their target population group(s).

#### **4.3.1.1 Rate Protective of Human Health from Chronic Exposure**

EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults. As previously indicated, exposure factor values specific to adults are recommended to protect against effects from long-term exposure. The value of 70 kg is based on the following information. In the analysis of the NHANES III database, median and mean values for female adults 18-74 years old are 65.8 and 69.5 kg, respectively (WESTAT, 2000). For males in the same age range, the median and mean values are 79.9 and 82.1 kg, respectively. The mean body weight value for men and women ages 18 to 74 years old from this survey is 75.6 kg (WESTAT, 2000). This mean value is higher than the mean value for adults ages 20-64 years old of 70.5 kg from a study by the National Cancer Institute (NCI) which primarily measured drinking water intake (Ershow and Cantor, 1989). The NCI study is described in the subsection on Drinking Water Intake Rates that follows (Section 4.3.2). The value from the NHANES III database is also higher than the value given in the revised EPA *Exposure Factors Handbook* (USEPA, 1997b), which recommends 71.8 kg for adults, based on the older NHANES II data. The Handbook also acknowledges the commonly used 70 kg value and encourages risk assessors to use values which most accurately reflect the exposed population. However, the point is also made that the 70 kg value is used in the derivation of cancer slope factors and unit risks that appear in IRIS. Consistency is advocated between the dose-response relationship and exposure factors assumed. Therefore, if a value higher than 70 kg is used, the assessor needs to adjust the dose-response relationship as described in the Appendix to Chapter 1, Volume 1 of the Handbook (USEPA, 1997b).

#### **4.3.1.2 Rates Protective of Developmental Human Health Effects**

As noted above, pregnant women may represent a more appropriate population for which to assess risks from exposure to chemicals in ambient waters in some cases, because of the potential for developmental effects in fetuses. In these cases, body weights representative of women of childbearing age may be appropriate to adequately protect offspring from such health effects. To determine a mean body weight value appropriate to this population, separate body weight values for women in individual age groups within the range of 15 to 44 years old were analyzed from the NHANES III data (WESTAT, 2000). The resulting median and mean body weight values are 63.2 and 67.3 kg, respectively. Ershow and Cantor (1989) present body weight values specifically for pregnant women included in the survey; median and mean weights are 64.4 and 65.8 kilograms, respectively. Ershow and Cantor (1989), however, do not indicate the ages of these pregnant women. Based on this information for women of childbearing age and pregnant women, EPA recommends use of a body weight value of 67 kg in cases where pregnant women are the specific population of concern and the chemical of concern exhibits reproductive and/or developmental effects (i.e., the critical effect upon which the RfD or POD/UF is based). Using the 67 kg assumption would result in lower (more protective) criteria than criteria based on 70 kg.

As discussed earlier, because infants and children generally have a higher rate of water and food consumption per unit body weight compared with adults, a higher intake rate per unit body weight may be needed when comparing estimated exposure doses with critical doses when RfDs are based on health effects in children. To calculate intake rates relevant to such effects, the body weight of children should be used. As with the default body weight for pregnant women, EPA is not recommending the development of additional AWQC (i.e., similar to drinking water health advisories) that focus on acute or short-term effects, since these are not seen routinely as having a meaningful role in the water quality criteria program. However, there may be circumstances where the consideration of exposures for these groups is warranted. Although the AWQC generally are based on chronic health effects data, they are intended to also be protective with respect to adverse effects that may reasonably be expected to occur as a result of elevated shorter-term exposures. EPA acknowledges this as a potential course of action and is, therefore, recommending these default values which EPA would consider in an appropriate circumstance and for States and authorized Tribes to utilize in such situations.

EPA is recommending an assumption of 30 kg as a default child's body weight to calculate AWQC to provide additional protection for children when the chemical of concern indicates health effects in children are of predominant concern (i.e., test results show children are more susceptible due to less developed immune systems, neurological systems, and/or lower body weights). The value is based on the mean body weight value of 29.9 kg for children ages 1 to 14 years old, which combines body weight values for individual age groups within this larger group. The mean value is based on body weight information from NHANES III for individual-year age groups between one and 14 years old (WESTAT, 2000). A mean body weight of 28 kg is obtained using body weight values from Ershow and Cantor (1989) for five age groups within this range of 0-14 years and applying a weighting method for different ages by population percentages from the U.S. Bureau of the Census. The 30 kg assumption is also consistent with the age range

for children used with the estimated fish intake rates. Unfortunately, fish intake rates for finer age group divisions are not possible due to the limited sampling base from the fish intake survey; there is limited confidence in calculated values (e.g., the mean) for such fine age groups. Given this limitation, the broad age category of body weight for children is suitable for use with the default fish intake assumption.

Given the hierarchy of preferences regarding the use of fish intake information (see Section 4.3.3), States may have more comprehensive data and prefer to target a more narrow, younger age group. If States choose to specifically evaluate toddlers, EPA recommends using 13 kg as a default body weight assumption for children ages 1 to 3 years old. The median and mean values of body weight for children 1 to 3 years old are 13.2 and 13.1 kg, respectively, based on an analysis of the NHANES III database (WESTAT, 2000). The NHANES III median and mean values for females between 1 and 3 years old are 13.0 and 12.9 kg, respectively, and are 13.4 and 13.4 kg for males, respectively. Median and mean body weight values from the earlier Ershow and Cantor (1989) study for children ages 1 to 3 years old were 13.6 and 14.1 kg, respectively. Finally, if infants are specifically evaluated, EPA recommends a default body weight of 7 kg based on the NHANES III analysis. Median and mean body weights for both male and female infants (combined) 2 months old were 6.3 and 6.3 kg, respectively, and for infants 3 months old were 7.0 and 6.9 kg, respectively. With the broader age category of males and females 2 to 6 months old, median and mean body weights were 7.4 and 7.4 kg, respectively. The NHANES analysis did not include infants under 2 months of age. Although EPA is not recommending body weight values for newborns, the NCHS National Vital Statistics Report indicates that, for 1997, the median birth weight ranged from 3 to 3.5 kg, according to WESTAT (2000).

Body weight values for individual ages within the larger range of 0-14 years are listed in the Exposure Assessment TSD for those States and authorized Tribes who wish to use body weight values for these individual groups. States and Tribes may wish to consider certain general developmental ages (e.g., infants, pre-adolescents, etc.), or certain specific developmental landmarks (e.g., neurological development in the first four years), depending on the chemical of concern. EPA encourages States and authorized Tribes to choose a body weight intake from the tables presented in the TSD, if they believe a particular age subgroup is more appropriate.

#### **4.3.2 Drinking Water Intake Rates**

The basis for the drinking water intake rates (also for the fish intake rates presented in Section 4.3.3) is the 1994-96 Continuing Survey of Food Intake by Individuals (CSFII) conducted by the U.S. Department of Agriculture (USDA, 1998). The CSFII survey collects dietary intake information from nationally representative samples of non-institutionalized persons residing in United States households. Households in these national surveys are sampled from the 50 states and the District of Columbia. Each survey collects daily consumption records for approximately 10,000 food codes across nine food groups. These food groups are (1) milk and milk products; (2) meat, poultry, and fish; (3) eggs; (4) dry beans, peas, legumes, nuts, and

seeds; (5) grain products; (6) fruit; (7) vegetables; (8) fats, oils, and salad dressings; and (9) sweets, sugars, and beverages. The survey also asks each respondent how many fluid ounces of plain drinking water he or she drank during each of the survey days. In addition, the CSFII collects household information, including the source of plain drinking water, water used to prepare beverages, and water used to prepare foods. Data provide “up-to-date information on food intakes by Americans for use in policy formation, regulation, program planning and evaluation, education, and research.” The survey is “the cornerstone of the National Nutritional Monitoring and Related Research Program, a set of related federal activities intended to provide regular information on the nutritional status of the United States population” (USDA, 1998).

The 1994-96 CSFII was conducted according to a stratified, multi-area probability sample organized using estimates of the 1990 United States population. Stratification accounted for geographic location, degree of urbanization, and socioeconomics. Each year of the survey consisted of one sample with oversampling for low-income households.

Survey participants provided two non-consecutive, 24-hour days of dietary data. Both days’ dietary recall information was collected by an in-home interviewer. Interviewers provided participants with an instructional booklet and standard measuring cups and spoons to assist them in adequately describing the type and amount of food ingested. If the respondent referred to a cup or bowl in their own home, a 2-cup measuring cup was provided to aid in the calculation of the amount consumed. The sample person could fill their own bowl or cup with water to represent the amount eaten or drunk, and the interviewer could then measure the amount consumed by pouring it into the 2-cup measure. The Day 2 interview occurred three to 10 days after the Day 1 interview, but not on the same day of the week. The interviews allowed participants “three passes” through the daily intake record to maximize recall (USDA, 1998). Proxy interviews were conducted for children aged six and younger and sampled individuals unable to report due to mental or physical limitations. The average questionnaire administration time for Day 1 intake was 30 minutes, while Day 2 averaged 27 minutes.

Two days of dietary recall data were provided by 15,303 individuals across the three survey years. This constitutes an overall two-day response rate of 75.9 percent. Survey weights were corrected by the USDA for nonresponse.

All three 1994-96 CSFII surveys are multistage, stratified-cluster samples. Sample weights, which project the data from a sampled individual to the population, are based on the probability of an individual being sampled at each stage of the sampling design. The sample weights associated with each individual reporting two days of consumption data were adjusted to correct for nonresponse bias.

The 1994-96 CSFII surveys have advantages and limitations for estimating per capita water (or fish) consumption. The primary advantage of the CSFII surveys is that they were designed and conducted by the USDA to support unbiased estimation of food consumption across the population in the United States and the District of Columbia. Second, the survey is designed to record daily intakes of foods and nutrients and support estimation of food consumption.

One limitation of the 1994-96 CSFII surveys is that individual food consumption data were collected for only two days—a brief period which does not necessarily depict “usual intake.” Usual dietary intake is defined as “the long-run average of daily intakes by an individual.” Upper percentile estimates may differ for short-term and longer-term data because short-term food consumption data tend to be inherently more variable. It is important to note, however, that variability due to duration of the survey does not result in bias of estimates of overall mean consumption levels. Also, the multistage survey design does not support interval estimates for many of the subpopulations of interest because of sparse representation in the sample. Subpopulations with sparse representation include Native Americans on reservations and certain ethnic groups. While these individuals are participants in the survey, they are not present in sufficient numbers to support consumption estimates.

Despite these limitations, the CSFII is considered one of the best sources of current information on consumption of water and fish-containing foods. The objective of estimating per capita water and fish consumption by the United States population is compatible with the statistical design and scope of the CSFII survey.

#### **4.3.2.1 Rate Protective of Human Health from Chronic Exposure**

EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with fish intake (i.e., drinking water intake varies, by and large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision. The results of the 1994-96 CSFII analysis indicate that the arithmetic mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values for adults 20 years and older are 1.1, 1.5, and 2.2 L/day, respectively (USEPA, 2000a). The 2 L/day value represents the 86<sup>th</sup> percentile for adults. These values can also be compared to data from an older National Cancer Institute (NCI) study, which estimated intakes of tapwater in the United States based on the USDA’s 1977-78 Nationwide Food Consumption Survey (NFCS). The arithmetic mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values for adults 20 - 64 years old were 1.4, 1.7, and 2.3 L/day, respectively (Ershow and Cantor, 1989). The 2 L/day value represents the 88<sup>th</sup> percentile for adults from the NCI study.

The 2 L/day assumption was used with the original 1980 AWQC National Guidelines and has also been used in EPA’s drinking water program. EPA believes that the newer studies continue to support the use of 2 L/day as a reasonable and protective consumption rate that represents the intake of most water consumers in the general population. However, individuals who work or exercise in hot climates could have water consumption rates significantly above 2

L/day, and EPA believes that States and Tribes should consider regional or occupational variations in water consumption.

#### **4.3.2.2 Rates Protective of Developmental Human Health Effects**

Based on the 1994-96 CSFII study data, EPA also recommends 2 L/day for women of childbearing age. The analysis for women of childbearing age (ages 15-44) indicate mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values of 0.9, 1.3, and 2.0 L/day, respectively. These rates compare well with those based on an analysis of tapwater intake by pregnant and lactating women by Ershow et al. (1991), based on the older USDA data, for women ages 15-49. Arithmetic mean, 75<sup>th</sup> and 90<sup>th</sup> percentile values were 1.2, 1.5, and 2.2 L/day, respectively, for pregnant women. For lactating women, the arithmetic mean, 75<sup>th</sup> and 90<sup>th</sup> percentile values were 1.3, 1.7, and 1.9 L/day, respectively.

As noted above, because infants and children have a higher daily water intake per unit body weight compared with adults, a water consumption rate measured for children is recommended for use when RfDs are based on health effects in children. Use of this water consumption rate should result in adequate protection for infants and children when setting criteria based on health effects for this target population. EPA recommends a drinking water intake of 1 L/day to, again, represent a majority of the population of children that consume drinking water. The results of the 1994-96 CSFII analysis indicate that for children from 1 to 10 years of age, the arithmetic mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values are 0.4, 0.6, and 0.9 L/day, respectively (USEPA, 2000a). The 1 L/day value represents the 93rd percentile for this group. The arithmetic mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values for smaller children, ages 1 to 3 years, are 0.3, 0.5, and 0.7 L/day, respectively. The 1 L/day value represents the 97th percentile of the group ages 1 to 3 years old. For the category of infants under 1 year of age, the arithmetic mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values are 0.3, 0.7, and 0.9 L/day, respectively. These data can similarly be compared to those of the older National Cancer Institute (NCI) study. The arithmetic mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values for children 1 to 10 years old were 0.74, 0.96, and 1.3 L/day, respectively. The mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values for children 1 to 3 years old in the NCI study were 0.6, 0.8, and 1.2 L/day, respectively. Finally, the mean, 75<sup>th</sup>, and 90<sup>th</sup> percentile values for infants less than 6 months old were 0.3, 0.3, and 0.6 L/day, respectively (Ershow and Cantor, 1989).

#### **4.3.2.3 Rates Based on Combining Drinking Water Intake and Body Weight**

As an alternative to considering body weight and drinking water intake rates separately, EPA is providing rates based on intake per unit body weight data (in units of ml/kg) in the Exposure Assessment TSD, with additional discussion on their use. These rates are based on self-reported body weights from the CSFII survey respondents for the 1994-96 data. While EPA intends to derive or revise national default criteria on the separate intake values and body weights, in part due to the strong input received from its State stakeholders, the ml/kg-BW/day values are provided in the TSD for States or authorized Tribes that prefer their use. It should be noted that in their 1993 review, EPA's Science Advisory Board (SAB) felt that using drinking water intake rate assumptions on a per unit body weight basis would be more accurate, but did not believe this change would appreciably affect the criteria values (USEPA, 1993).



### 4.3.3 Fish Intake Rates

The basis for the fish intake rates is the 1994-96 CSFII conducted by the USDA, and described above in Section 4.3.2.

#### 4.3.3.1 Rates Protective of Human Health from Chronic Exposure

EPA recommends a default fish intake rate of 17.5 grams/day to adequately protect the general population of fish consumers, based on the 1994 to 1996 data from the USDA's CSFII Survey. EPA will use this value when deriving or revising its national 304(a) criteria. This value represents the 90<sup>th</sup> percentile of the 1994-96 CSFII data. This value also represents the uncooked weight estimated from the CSFII data, and represents intake of freshwater and estuarine finfish and shellfish only. For deriving AWQC, EPA has also considered the States' and Tribes' needs to provide adequate protection from adverse health effects to highly exposed populations such as recreational and subsistence fishers, in addition to the general population. Based on available studies that characterize consumers of fish, recreational fishers and subsistence fishers are two distinct groups whose intake rates may be greater than the general population. It is, therefore, EPA's decision to discuss intakes for these two groups, in addition to the general population.

EPA recommends default fish intake rates for recreational and subsistence fishers of 17.5 grams/day and 142.4 grams/day, respectively. These rates are also based on uncooked weights for fresh/estuarine finfish and shellfish only. However, because the level of fish intake in highly exposed populations varies by geographical location, EPA suggests a four preference hierarchy for States and authorized Tribes to follow when deriving consumption rates that encourages use of the best local, State, or regional data available. A thorough discussion of the development of this policy method and relevant data sources is contained in the Exposure Assessment TSD. The hierarchy is also presented here because EPA strongly emphasizes that States and authorized Tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates.

The recommended four preference hierarchy is intended for use in evaluating fish intake from fresh and estuarine species only. Therefore, to protect humans who additionally consume marine species of fish, the marine portion should be considered an *other source of exposure* when calculating an RSC for dietary intake. Refer to the Exposure Assessment TSD for further discussion. States and Tribes need to ensure that when evaluating overall exposure to a contaminant, marine fish intake is not double-counted with the other dietary intake estimate used. Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., fresh/estuarine and marine species) is more appropriate for protecting the population of concern may do so, provided that the marine intake component is not double-counted with the RSC estimate. Tables of fish consumption intakes based on the CSFII in the TSD provide rates for fresh/estuarine species, marine species, and total (combined) values to facilitate this option for

States and Tribes. Throughout this section, the terms “fish intake” or “fish consumption” are used. These terms refer to the consumption of finfish and shellfish, and the CSFII survey includes both. States and Tribes should ensure that when selecting local or regionally-specific studies, both finfish and shellfish are included when the population exposed are consumers of both types.

EPA’s first preference is that States and authorized Tribes use the results from fish intake surveys of local watersheds within the State or Tribal jurisdiction to establish fish intake rates that are representative of the defined populations being addressed for the particular waterbody. Again, EPA recommends that data indicative of fresh/estuarine species only be used which is, by and large, most appropriate for developing AWQC. EPA also recommends the use of uncooked weight intake values, which is discussed in greater detail with the fourth preference. States and authorized Tribes may use either high-end values (such as the 90<sup>th</sup> or 95<sup>th</sup> percentile values) or average values for an identified population that they plan to protect (e.g., subsistence fishers, sport fishers, or the general population). EPA generally recommends that arithmetic mean values should be the lowest value considered by States or Tribes when choosing intake rates for use in criteria derivation. When considering geometric mean (median) values from fish consumption studies, States and authorized Tribes need to ensure that the distribution is based on survey respondents who reported consuming fish because surveys based on both consumers and nonconsumers can often result in median values of zero. If a State or Tribe chooses values (whether the central tendency or high-end values) from studies that particularly target high-end consumers, these values should be compared to high-end fish intake rates for the general population to make sure that the high-end consumers within the general population would be protected by the chosen intake rates. EPA believes this is a reasonable procedure and is also consistent with the recent Great Lakes Water Quality Initiative (known as the “GLI”) (USEPA, 1995). States and authorized Tribes may wish to conduct their own surveys of fish intake, and EPA guidance is available on methods to conduct such studies in *Guidance for Conducting Fish and Wildlife Consumption Surveys* (USEPA, 1998). Results from broader geographic regions in which the State or Tribe is located can also be used, but may not be as applicable as results from local watersheds. Since such studies would ultimately form the basis of a State or Tribe’s AWQC, EPA would review any surveys of fish intake for consistency with the principles of EPA’s guidance as part of the Agency’s review of water quality standards under Section 303(c).

If surveys conducted in the geographic area of the State or Tribe are not available, EPA’s second preference is that States and authorized Tribes consider results from existing fish intake surveys that reflect similar geography and population groups (e.g., from a neighboring State or Tribe or a similar watershed type), and follow the method described above regarding target values to derive a fish intake rate. Again, EPA recommends the use of uncooked weight intake values and the use of fresh/estuarine species data only. Results of existing local and regional surveys are discussed in greater detail in the TSD.

If applicable consumption rates are not available from local, State, or regional surveys, EPA’s third preference is that States and authorized Tribes select intake rate assumptions for different population groups from national food consumption surveys. EPA has analyzed one such

national survey, the 1994-96 CSFII. As described in Section 4.3.2, this survey, conducted annually by the USDA, collects food consumption information from a probability sample of the population of all 50 states. Respondents to the survey provide two days of dietary recall data. A detailed description of the combined 1994-96 CSFII survey, the statistical methodology, and the results and uncertainties of the EPA analyses are provided in a separate EPA report (USEPA, 2000b). The Exposure Assessment TSD for this Methodology presents selected results from this report including point and interval estimates of combined finfish and shellfish consumption for the mean, 50<sup>th</sup> (median), 90<sup>th</sup>, 95<sup>th</sup>, and 99<sup>th</sup> percentiles. The estimated fish consumption rates are by fish habitat (i.e., freshwater/estuarine, marine and all habitats) for the following population groups: (1) all individuals; (2) individuals age 18 and over; (3) women ages 15-44; and (4) children age 14 and under. Three kinds of estimated fish consumption rates are provided: (1) per capita rates (i.e., rates based on consumers and nonconsumers of fish from the survey period—refer to the TSD for further discussion); (2) consumers-only rates (i.e., rates based on respondents who reported consuming finfish or shellfish during the two-day reporting period); and (3) per capita consumption by body weight (i.e., per capita rates reported as milligrams of fish per kilogram of body weight per day).

EPA's fourth preference is that States and authorized Tribes use as fish intake assumptions the following default rates, based on the 1994-96 CSFII data, that EPA believes are representative of fish intake for different population groups: 17.5 grams/day for the general adult population and sport fishers, and 142.4 grams/day for subsistence fishers. These are risk management decisions that EPA has made after evaluating numerous fish intake surveys. These values represent the uncooked weight intake of freshwater/estuarine finfish and shellfish. As with the other preferences, EPA requests that States and authorized Tribes routinely consider whether there is a substantial population of sport fishers or subsistence fishers when developing site-specific estimates, rather than automatically basing them on the typical individual. Because the combined 1994-96 CSFII survey is national in scope, EPA will use the results from this survey to estimate fish intake for deriving national criteria. EPA has recognized the data gaps and uncertainties associated with the analysis of the 1994-96 CSFII survey in the process of making its default recommendations. The estimated mean of freshwater and estuarine fish ingestion for adults is 7.50 grams/day, and the median is 0 grams/day. The estimated 90<sup>th</sup> percentile is 17.53 grams/day; the estimated 95<sup>th</sup> percentile is 49.59 grams/day; and the estimated 99<sup>th</sup> percentile is 142.41 grams/day. The median value of 0 grams/day may reflect the portion of individuals in the population who never eat fish as well as the limited reporting period (2 days) over which intake was measured. By applying as a default 17.5 grams/day for the general adult population, EPA intends to select an intake rate that is protective of a majority of the population (again, the 90<sup>th</sup> percentile of consumers and nonconsumers according to the 1994-96 CSFII survey data). Trophic level breakouts are: TL2 = 3.8 grams/day; TL3 = 8.0 grams/day; and TL4 = 5.7 grams/day. EPA further considers 17.5 grams/day to be indicative of the average consumption among sport fishers based on averages in the studies reviewed, which are presented in the Exposure Assessment TSD. Similarly, EPA believes that the assumption of 142.4 grams/day is within the range of average consumption estimates for subsistence fishers based on the studies reviewed. Experts at the 1992 National Workshop that initiated the effort to revise this Methodology acknowledged that the national survey high-end values are representative of

average rates for highly exposed groups such as subsistence fishermen, specific ethnic groups, or other highly exposed people. EPA is aware that some local and regional studies indicate greater consumption among Native American, Pacific Asian American, and other subsistence consumers, and recommends the use of those studies in appropriate cases, as indicated by the first and second preferences. Again, States and authorized Tribes have the flexibility to choose intake rates higher than an average value for these population groups. If a State or authorized Tribe has not identified a separate well-defined population of high-end consumers and believes that the national data from the 1994-96 CSFII are representative, they may choose these recommended rates.

As indicated above, the default intake values are based on the uncooked weights of the fish analyzed. There has been some question regarding whether to use cooked or uncooked weights of fish intake for deriving the AWQC. Studies show that, typically, with a filet or steak of fish, the weight loss in cooking is about 20 percent; that is, the uncooked weight is approximately 20 percent higher (Jacobs et al., 1998). This obviously means that using uncooked weights results in a slightly higher intake rate and slightly more stringent AWQC. In researching consumption surveys for this proposal, EPA has found that some surveys have reported rates for cooked fish, others have reported uncooked rates, and many more are unclear as to whether cooked or uncooked rates are used. The basis of the CSFII survey was prepared on *as consumed* intakes; that is, the survey respondents estimated the weight of fish that they consumed. This was also true with the GLI (which was specifically based on studies describing consumption rates of cooked fish) and, by and large, cooked fish is what people consume. However, EPA's *Guidance For Assessing Chemical Contaminant Data For Use In Fish Advisories* recommends analysis and advisories based on uncooked fish (USEPA, 1997a). EPA considered the potential confusion over the fact that the uncooked weights are used in the fish advisory program. Further, the measures of a contaminant in fish tissue samples that are applicable to compliance monitoring and the permitting program are related to the uncooked weights. The choice of intakes is also complicated by factors such as the effect of the cooking process, the different parts of a fish where a chemical may accumulate, and the method of preparation.

After considering all of the above (in addition to public input received), EPA will derive its national default criteria based on the uncooked weight fish intakes. The Exposure Assessment TSD provides additional guidance on site-specific modifications. Specifically, an alternate approach is described for calculating AWQC with the *as consumed* weight—which is more directly associated with human exposure and risk—and then adjusting the value by the approximate 20 percent loss to an uncooked equivalent (thereby representing the same relative risk as the *as consumed* value). This approach results in a different AWQC value (than using the uncooked weights) and represents a more direct translation of the *as consumed* risk to the uncooked equivalent. However, EPA understands that it is more scientifically rigorous and may be too intensive of a process for States and Tribes to rely on. The option is presented in the TSD to offer States and authorized Tribes greater flexibility with their water quality standards program.

The default fish intake values also reflect specific designations of species classified in accordance with information regarding the life history of the species or based on landings information from the National Marine Fisheries Service. Most significantly, salmon has been

reclassified from a freshwater/estuarine species to a marine species. As marine harvested salmon represents approximately 99 percent of salmon consumption in the 1994-96 CSFII Survey, removal reduces the overall fresh/estuarine fish consumption rate by 13 percent. Although they represent a very small percentage of freshwater/estuarine intake, land-locked and farm-raised salmon consumed by 1994-96 CSFII respondents are still included. The rationale for the default intake species designations is explained in the Exposure Assessment TSD. Once again, EPA emphasizes the flexibility for States and authorized Tribes to use alternative assumptions based on local or regional data to better represent their population groups of concern.

#### **4.3.3.2 Rates Protective of Developmental Human Health Effects**

Exposures resulting in health effects in children or developmental effects in fetuses may be of primary concern. As discussed at the beginning of this section on exposure factors used, in a situation where acute or sub-chronic toxicity and exposure are the basis of an RfD (or POD/UF), EPA will consider basing its national default criteria on children or women of childbearing age, depending on the target population at greatest risk. EPA recommends that States and authorized Tribes use exposure factors for children or women of childbearing age in these situations. As stated previously, EPA is not recommending the development of additional AWQC but is acknowledging that basing a criterion on these population groups is a potential course of action and is, therefore, recommending the following default intake rates for such situations.

EPA's preferences for States and authorized Tribes in selecting values for intake rates relevant for children is the same as that discussed above for establishing values for average daily consumption rates for chronic effects; i.e., in decreasing order of preference, results from fish intake surveys of local watersheds, results from existing fish intake surveys that reflect similar geography and population groups, the distribution of intake rates from nationally based surveys (e.g., the CSFII), or lastly, the EPA default rates. When an RfD is based on health effects in children, EPA recommends a default intake rate of 156.3 grams/day for assessing those contaminants that exhibit adverse effects. This represents the 90<sup>th</sup> percentile consumption rate for actual consumers of freshwater/estuarine finfish and shellfish for children ages 14 and under using the combined 1994 to 1996 results from the CSFII survey. The value was calculated based on data for only those children who ate fish during the 2-day survey period, and the intake was averaged over the number of days during which fish was actually consumed. EPA believes that by selecting the data for consumers only, the 90<sup>th</sup> percentile is a reasonable intake rate to approximate consumption of fresh/estuarine finfish and shellfish within a short period of time for use in assessments where adverse effects in children are of primary concern. As discussed previously, EPA will use a default body weight of 30 kg to address potential acute or subchronic effects from fish consumption by children. EPA is also providing these default intake values for States and authorized Tribes that choose to provide additional protection when developing criteria that they believe should be based on health effects in children. This is consistent with the rationale in the recent GLI (USEPA, 1995) and is an approach that EPA believes is reasonable. Distributional information on intake values relevant for assessing exposure when health effects to children are of concern is presented in the Exposure Assessment TSD.

There are also cases in which pregnant women may be the population of most concern, due to the possibility of developmental effects that may result from exposures of the mother to toxicants. In these cases, fish intake rates specific to females of childbearing age are most appropriate when assessing exposures to developmental toxicants. When an RfD is based on developmental toxicity, EPA proposes a default intake rate of 165.5 grams/day for assessing exposures for women of childbearing age from contaminants that cause developmental effects. This is equivalent to the 90<sup>th</sup> percentile consumption rate for actual consumers of freshwater/estuarine finfish and shellfish for women ages 15 to 44 using the combined 1994 to 1996 results from the CSFII survey. As with the rate for children, this value represents only those women who ate fish during the 2-day survey period. As discussed previously, EPA will use a default body weight of 67 kg for women of childbearing age.

#### **4.3.3.3 Rates Based on Combining Fish Intake and Body Weight**

As with the drinking water intake values, EPA is providing values for fish intake based on a per unit body weight basis (in units of mg/kg) in the Exposure Assessment TSD. These rates use the self-reported body weights of the 1994-96 CSFII survey. Again, while EPA intends to derive or revise national default criteria on the separate intake values and body weights, the mg/kg-BW/day values are provided in the TSD for States or authorized Tribes that prefer their use.

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